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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,303	02/18/2004	Rafail Zubok	532-3X9a	4832

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EXAMINER

WOODALL, NICHOLAS W

ART UNIT PAPER NUMBER

3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/781,303

Applicant(s)

ZUBOK ET AL.

Examiner

Nicholas Woodall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9 and 12-14 is/are rejected.
- 7) ☒ Claim(s) 6, 10 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>06/15/2004; 01/28/2005</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Specification***

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. The abstract of the disclosure is objected to because the abstract comprises more than 150 words. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 1 there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites "a retaining clip" with the bone screw being only functionally recited, i.e. "For an intervertebral disc replacement device having a flange defining at least one bone screw hole for receipt therethrough of a bone screw", thus indicating that the claim is directed to the subcombination, "a retaining clip". However, in line 9, applicant positively recites the bone screw as part of the invention, i.e. "at least one lateral flange extending from said body member, partially received over a portion of said bone screw...", thus indicating that the combination, a retaining clip and a bone screw, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claim 1 will be considered as being drawn to the subcombination, a retaining clip.

6. There exists an inconsistency between the language of claim 1 and that of the claim 5 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 1, line 3, applicant recites "a retaining clip" with the at least one mounting hole being only functionally recited, i.e. "For an intervertebral disc replacement device having a flange defining at least one bone screw hole for receipt therethrough of a bone screw and defining at least one mounting hole", thus indicating that the claim is directed to the subcombination, "a retaining clip". However, in claim 5, lines 1-3, applicant positively

recites the mounting hole as part of the invention, i.e. "said at least one mounting hole....", thus indicating that the combination, retaining clip and the at least one mounting hole, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 1 and 5 will be considered as being drawn to the subcombination, a retaining clip.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

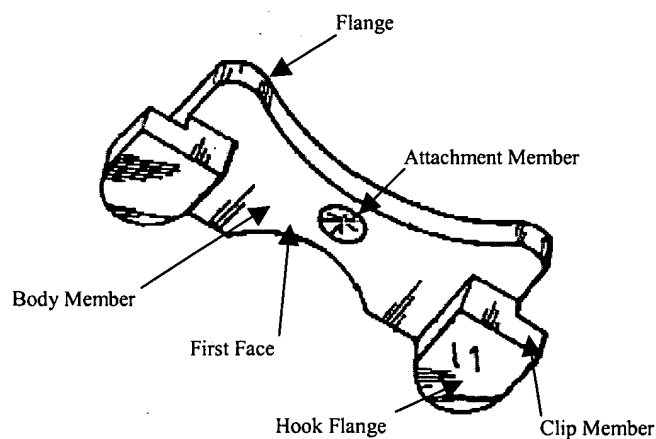
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 1, 3, 4, and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Assaker (U.S. Patent 6,652,525).

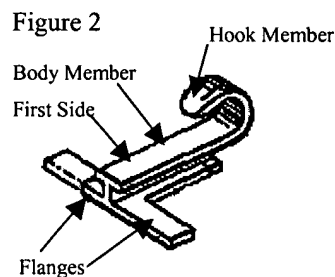
Regarding claim 1, Assaker discloses a device comprising a body member having a first side, a hook flange extending from the body member, and at least one lateral flange extending from the body member (see Figure 1 below). Regarding claim 3, Assaker discloses a device wherein the body member further comprises at least one attachment member protruding from the first side of the body member. Regarding claim 4, Assaker discloses a device wherein the hook flange includes a clip member protruding from therefrom in a direction toward the first side of the body member. Regarding claim 7, the at least one attachment member is capable of being used as a snapping attachment member.

Figure 1



9. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Hameister (U.S. Patent 4,457,484).

Regarding claim 1, Hameister discloses a device comprising a body member having a first side, a hook flange extending from the body member, and at least one lateral flange extending from the body member (see Figure 2 below). Regarding claim 2, Hameister discloses a device wherein the at least one lateral flange extending from the body member comprises two lateral flanges extending from the body member in substantially opposite directions.



### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 8, 9, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rygg (U.S. Patent 3,278,107) in view of Powers (U.S. Publication 2005/0033430).

Regarding claim 8, Rygg discloses a kit comprising an applicator and clip. The applicator includes a first applicator arm and a second applicator arm each extending in substantially the same direction from a common bending elbow (see Figure 3 below).

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The kit further includes a first clip removably secured to the first end of the first applicator arm. Regarding claim 9, Rygg discloses an applicator wherein the first applicator arm includes a protruding member extending from the first end of the first applicator arm. Rygg fails to disclose the kit comprising an enclosure (claim 8). Powers teaches an enclosure capable of holding a set of sterilized surgical instruments that is made of a non-permeable material, such as plastic (page 2 paragraph 021), and the enclosure is sealed and devoid of substantially moist air by using a seal or cover that is removably attached to the enclosure (page 2 paragraph 023) in order to maintain the sterility of the surgical instruments until such time as the instruments are to be assessed (page 2 paragraph 020). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Rygg wherein the device included an enclosure capable of holding a set of sterilized surgical instruments in view of Powers in order to maintain the sterility of the surgical instruments until such time as the instruments are to be assessed.

#### ***Allowable Subject Matter***

12. Claims 6, 10, and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references that the examiner felt were relevant to the prior art.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWW



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